REMARKS

Following entry of the above amendments to the claims, claims 1, 5-6, 11, and 18 remain pending in this application. Reconsideration of the outstanding rejection and early allowance of this application are respectively solicited.

Claims 1, 5-6, 11, and 18 have been amended to more clearly point out Applicants' invention. Claims 2-4, 7-10, 12-17 and 19 have been canceled. No new matter has been introduced by any of these amendments.

Objection to Drawings

In the outstanding Office Action, the Examiner objected to the drawings under 37 C.F.R. § 1.83(a) because they allegedly fail to indicate the protein profiling system. While not acceding to the Examiner's characterization, Applicants will make the necessary corrections to the drawings upon the indication of allowable subject matter in this application.

Rejection Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-9 under 35 U.S.C. § 102(b) as allegedly being anticipated by Yates *et al.*, U.S. Patent No. 5,538,897. Applicants respectfully traverse this rejection.

In support of the outstanding rejection, the Examiner has alleged that "Yates et al teaches the use of mass spectrometry fragment patterns to identify amino acid sequences in databases.

. . . . The present invention can be used in connection with diagnostic applications such as some forms of cancer, genetic disease and cystic fibrosies as recited in claims 2, 3, 8, and 9 (col. 17, lines 62-67 and col. 18, lines 25-38).

First, Applicants respectfully note that Yates does not, in fact, actually teach that his system may be used in diagnostic applications. That is, in the portion cited by the Examiner as allegedly supporting the outstanding rejection, Yates discloses that "[i]mplementation of these approach is believed to involve significant difficulties."

Yates, however, does not teach or suggest how to overcome the "significant difficulties" associated with his system for diagnostics. Yates also does not include a single example of the system being used in a diagnostic application to show that these "significant difficulties" could be overcome in practice. Thus, Yates does not enable one skilled in the art to make and use such a dianostic system, much less the presently claimed invention.

Nevertheless, even assuming, *arguendo*, that the Examiner's characterization of the reference is accurate, Yates still does not teach or suggest the presently claimed invention.

More specifically, as set forth in amended claim 1, the present invention is directed to a protein profiling system for detecting protein biomarkers of cancer. This system determines these protein biomarkers by comparing protein profiles from at least two samples <u>from the same patient</u>. One of these samples contains only normal tissue, while the other sample contains one or more tumor cells (and possibly some normal tissue). Yates does not teach or suggest such a system.

Rather, at most, Yates suggests a system that includes a library of protein profiles to which a sample protein profile may be compared. Significantly, Yates does not teach or suggest that the reference protein profile(s) be obtained from the same patient as the sample being tested. Such an arrangement, as employed in the claimed system, substantially reduces the chances for incorrect diagnosis that may arise, for example, from natural variations in protein structure normally observed from one patient to another.

Thus, the present system, by utilizing a reference sample obtained from the same patient as the test sample provides a significantly better result, for in terms of accuracy and lack of false positives, than the one suggested by Yates.

Moreover, the Yates system is utterly <u>useless</u> for diagnosing new or variant cancers (or, indeed, any new disease). In particularly, the Yates system relies on a database of <u>known</u> protein profiles, both normal and diseased. Thus, if a test sample from a given patient does not match one of the profiles in the Yates database, then an incorrect result is obtained.

In marked contrast, by use of the presently claimed system, a test sample from a given patient is compared to a normal sample from the same patient. Thus, <u>any</u> difference between the protein profiles (normal vs. test) in the inventive system is indicative of a cancer, irrespective of whether the cancer is known or if this is the first ever diagnosis of such cancer. The latter result simply could not be obtained with the Yates system.

Applicants therefore respectfully request the Examiner to reconsider and withdraw the outstanding rejection.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned attorney, Donald R. McPhail, at the telephone number listed below. Favorable consideration and prompt allowance are earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP

Mark L. Fleshner
Registration No. 34,596
Donald R. McPhail
Registration No. 35,811

P.O. Box 221200
Chantilly, VA 20153-1200
703 502-9440
Date: June 16, 2003
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